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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/610,118	06/30/2000	Samantha J. Busfield	7853-211	6846

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EXAMINER	
HUYNH, PHUONG N	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/610,118	BUSFIELD ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *252 and 265-277* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *252, and 265-277* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 252, and 265-277 are pending.

2. The following new grounds of rejections are necessitated by the amendment filed 5/21/04.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 266-276 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble "The antibody of claim 265" in claims 266-271 should have been "The antibody or antigen binding portion of claim 265".

The "antibody is conjugated to a therapeutic or drug moiety" in claim 272 lacks antecedent basis in base claim 265. It is suggested that claim 272 be rewritten to "A conjugated antibody or antigen binding portion thereof of claim 265 wherein the antibody is conjugated to a therapeutic or drug moiety".

"The antibody of claim 272" in claim 273 should have been "The conjugated antibody of claim 272..."

"The antibody of claim 275" in claim 274 should have been "The conjugated antibody of claim 272..."

"The antibody of claim 274" in claim 275 should have been "The conjugated antibody of claim 272..."

"A kit comprising an antibody or fragment thereof" in claim 276 has no antecedent basis in base claim 265 or 274. It is suggested that claim 276 be rewritten "A kit comprising the antibody or antigen binding portion thereof of claim 265 or 274 and instructions for use".

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 252 and 265-277 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 43-66 of copending Application No. 09/829,495 and claims 26-29, 33-47, 53-54, 65-79 and 87-90 of 09/503,387.

Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The instant claims are drawn to antibody or antigen binding portion thereof which immunospecifically binds to SEQ ID NO: 3, wherein the antibody or antigen binding portion thereof comprises: a) a variable heavy (W-1) complementary determining region (CDR) 1 comprising the amino acid sequence of SEQ ID NO: 61 or an amino acid sequence of a VH CDR1 encoded by the CDNA insert of the plasmid deposited with the ATCC as patent deposit number PTA-2442; b) a VH CDR2 comprising the amino acid sequence of SEQ INO:62 or an amino acid sequence of a VH CDR2 encoded by the CDNA insert of the plasmid deposited with the ATCC as patent deposit number PTA-2442; c) a VH CDR3 comprising the amino acid sequence of SEQ ID NO:63 or an amino acid sequence of a VH CDR3 encoded by the CDNA insert of the plasmid deposited with the ATCC as patent deposit number PTA-2442; d) a variable light (VL) CDRI comprising the amino acid sequence of SEQ ID NO:64 or an amino acid sequence of a VL CDRI encoded by the CDNA insert of the plasmid deposited with the ATCC as patent deposit number PTA-2442; e) a VL CDR2 comprising the amino acid sequence of SEQ ID NO:65 or an amino acid sequence of a VL CDR2 encoded by the CDNA insert of the plasmid deposited with the ATCC as patent deposit number PTA-2442; and f) a VL CDR3 comprising the amino acid sequence of SEQ ID NO:66 or an amino acid sequence of a VL CDR3 encoded by the CDNA insert of the plasmid deposited with the ATCC as patent deposit number PTA-2442

wherein the antibody is a monoclonal antibody (claim 266), a human antibody (claim 267), a humanized antibody (claim 268), a Fab fragment (claim 269), a F(ab')2 fragment (claim 270), an scFv (claim 271), the antibody is conjugated to a therapeutic or drug moiety (claims 272-273), the antibody is conjugated to a detectable substance (claims 274-275), a kit comprising said antibody (claim 276) and a pharmaceutical composition comprising said antibody and a pharmaceutically acceptable carrier (claim 277).

Claim 55 of 09/829,495 recites an antibody or antigen-binding fragment thereof which immunospecifically binds to a TANGL268 antigen, wherein the antibody or antigen-binding fragment thereof comprises the variable heavy (VH) chain complementarity determining regions (CHCDR1, VHCDR2 and VHCDR3) and the variable light (VL) chain complementarity determining regions (VLCDR1, VLCDR2 and VLCDR3) comprising the following sequences: VHCDR1: SEQ ID NO: 61; VHCDR2 SEQ ID NO: 62; VHCDR3 SEQ ID NO: 63; VLCDR1 SEQ ID NO: 64; VLCDR2 SEQ ID NO: 65 and VLCDR3 SEQ ID NO: 66 wherein the antibody is monoclonal (claim 56), a human antibody (claim 57), a humanized antibody (claim 58), a Fab fragment (claim 59), a F(ab')2 fragment (claim 60), an scFv (claim 61), the antibody is conjugated to a therapeutic or drug moiety (claims 62), the antibody is conjugated to a detectable substance (claims 63-64), a kit comprising said antibody (claim 65) and a pharmaceutical composition comprising said antibody and a pharmaceutically acceptable carrier (claim 66).

Claim 26 of 09/503,387 recites a substantially purified non-human antibody or fragment thereof which specifically binds to a polypeptide of the amino acid sequence of SEQ ID NO: 3 or the amino acid sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Accession Number 207180 wherein the antibody is monoclonal (claims 27, 29, 71), a human antibody (claim 71), a humanized antibody (claims 28, and 71), the antibody is conjugated to a therapeutic or drug moiety (claims 33, 72), the antibody is conjugated to a detectable substance (claims 34-35, 73-74), a kit comprising said antibody (claim 53-54, and 85-79) and a pharmaceutical composition comprising said antibody and a pharmaceutically acceptable carrier (claim 66). Claim 41 of 09/503,387 recites a substantially purified non-human antibody or fragment thereof which specifically binds to an extracellular domain of the amino acid sequence of SEQ ID NO: 3, wherein the antibody is a monoclonal, a chimric antibody (claim 42), humanized antibody (claim 43), a human antibody (claim 44), conjugated to a therapeutic moiety (claim 45), linked to a detectable substance (claim 46), linked to a detectable substance such as

enzyme, prosthetic group, fluorescent material, luminescent material, bioluminescent material, or radioactive material (claim 47).

However, SEQ ID NO: 3 is a human TANGO 268 protein encoded by the cDNA insert of plasmid with the ATCC Accession Number 207180 or the patent deposit Number PTA-225 (page 11 and page 146 of instant application). The antibody and binding fragment that binds to SEQ ID NO: 3 of claim 265 of instant is the same antibody or binding fragment thereof that binds to human TANGO268 antigen encoded by the cDNA insert of plasmid with the ATCC Accession Number 207180 as set forth in claim 55 09/829,495 and claim 26 of 09/503,387 because claim 55 recites an antibody or antigen-binding thereof which immunospecifically binds to a TANGO268 antigen and Claim 26 of 09/503,387 recites a substantially purified non-human antibody or fragment thereof which specifically binds to a polypeptide of the amino acid sequence of SEQ ID NO: 3 or the amino acid sequence encoded by the cDNA insert of the plasmid deposited with ATCC as Accession Number 207180. Further the antibody or antigen-binding fragment thereof of claim 265 of instant comprises the same VHCRDR1 of SEQ ID NO: 61, VHCDR2 of SEQ ID NO: 62, VHCDR3 of SEQ ID NO: 63; VLCDR1 of SEQ ID NO: 64, VLCDR2 of SEQ ID NO: 65 and VLCDR3 of SEQ ID NO: 66 as that of claim 55 of 09/829,495. Therefore, the monoclonal antibody in claim 266 of instant application appears to be the same monoclonal antibody as that of claim 56 of 09/829,495 and claims 27, 29, 71 of 09/503,387 because of these antibodies and binding fragment thereof have the same binding specificity. The human antibody in claim 267 of instant application appears to be the same human antibody as that of claim 57 of 09/829,495 and claim 71 of 09/503,387. The humanized antibody in claim 268 of instant application appears to be the same humanized antibody as that of claim 58 of 09/829,495 and claims 28, and 71of 09/503,387. The humanized antibody in claim 268 of instant application appears to be the same humanized antibody as that of claim 58 of 09/829,495 and claims 28, and 71of 09/503,387. The Fab fragment in claim 269 of instant application appears to be the same Fab fragment as that of claim 59 of 09/829,495. The (Fab')2 fragment in claim 270 of instant application appears to be the same Fab fragment as that of claim 60 of 09/829,495. The scFv antibody in claim 271 of instant application appears to be the same scFv antibody as that of claim 61 of 09/829,495. The conjugated antibody in claims 272-273 of instant application appears to be the same conjugated antibody as that of claim 62 of 09/829,495 and claims 33 and 72 of 09/503,387. The conjugated antibody in claim 274 of instant application appears to be the same conjugated antibody as that of claim 63 of 09/829,495 and claims 34 and 73 of 09/503,387. The

conjugated antibody in claim 275 of instant application appears to be the same conjugated antibody as that of claim 64 of 09/829,495 and claims 35 and 74 of 09/503,387. The kit comprising the antibody mentioned above in claim 276 of instant application appears to be the same kit comprising the same antibody as that of claim 65 of 09/829,495 and claims 53-54 and 75-79 of 09/503,387. The pharmaceutical composition comprising the same antibody in claim 277 of instant application appears to be the same pharmaceutical composition comprising the same antibody as set forth in claim 66 of 09/829,495. Finally, the antibody and binding fragment of instant application would also bind to an extracellular domain of the amino acid sequence of SEQ ID NO: 3 as set forth in claims 41-47 of 09/503,387.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. No claim is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (703) 872-9306.

10. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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